## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA NEWPORT NEWS DIVISION

IN RE SUBPOENA FOR DOCUMENTS ISSUED TO PENINSULA PATHOLOGY ASSOCIATES

Case No. 4:22-mc-00001-AWA-DEM

Related Case: S.D.N.Y.: 1:20-cv

5589-GBD

REPLY IN SUPPORT OF MOTION TO QUASH

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#### INTRODUCTION

The question before the Court is whether to quash a time-barred subpoena seeking burdensome discovery of confidential human subject research and the financial records of a nonparty whose sole connection to the underlying case is involvement in a study that American International Industries ("AII") deems adverse to its litigation interests. Some context is in order. AII has spent the last several years trying—repeatedly, in courts across the country—to discover the protected identities of the subjects of talc studies like Dr. Emory's. These efforts have been uniformly rejected, in numerous recent cases that Peninsula discussed in its brief. Remarkably, AII ignores all but one of these decisions entirely. And while AII tries to make the Court's task seem complicated by, among other things, filing nearly 700 pages of material, it really is quite simple because AII does not cite a single case where a court has permitted the discovery they seek—let alone in response to a nonparty subpoena. This Court should not be the first.

On timeliness, AII does not dispute (nor could it) that under the operative court orders, fact discovery closed in November 2021, and expert discovery—save for several depositions continued for scheduling reasons—closed in July 2022. That the *Gref* parties may have conducted certain limited party discovery after those deadlines does not somehow supersede a court-ordered schedule; parties cannot override judicial orders by informal agreement. *See* Fed. R. Civ. P. 16.

Turning to burden under Rule 45(d)(3)(A)(iv), AII's contention that the discovery it seeks is "critical" vastly exaggerates the relevance of the Article to the *Gref* litigation. AII contends that two of Mr. Gref's experts rely heavily on the Article. But both of these experts cite literally

<sup>&</sup>lt;sup>1</sup> A detailed account of AII's efforts on this front is set out in Ex. 1, Pl.'s Ltr., *Gref v. Am. Int'l Indus.*, et al., No. 1:20-cv-5589 (S.D.N.Y. Nov. 21, 2022), ECF No. 282 (hereafter, "*Gref* Ltr."). And AII itself acknowledges that its focus is broader than just the underlying *Gref* litigation. *See* Opp. 23 (arguing that AII needs the information sought by the Subpoena not only for "cross-examination of experts in [*Gref*]," but also other "cases pending throughout the nation").

hundreds of studies in their reports and make only passing reference to the Article. That AII is overstating its need for the discovery at issue is underscored by its failure to seek this supposedly "critical" discovery until a year after discovery closed despite being familiar with Dr. Emory's study for years—another point AII does not even attempt to address. And while AII posits that the Court should reject Peninsula's burden arguments because Peninsula is involved in other litigations—no matter that it is not involved in this litigation—that is nonsensical. Under AII's argument, anyone frequently involved in litigation (say, the Commonwealth of Virginia) would be foreclosed from ever making a burden objection under Rule 45. That is not the law. And AII's argument contravenes controlling precedent, which AII self-servingly misquotes.

As for whether confidential human subject information should be protected under Rule 45(d)(3)(A)(iii), AII's arguments rely on the wrong federal rule, ignore recent decisions involving the exact issue presented here, and fail to cite a single decision actually supporting disclosure.

Finally, AII only halfheartedly responds to Peninsula's sanctions argument, failing to address any of the case law Peninsula cited or citing any relevant authority of its own.

The Court should quash the Subpoena and order AII to bear Peninsula's fees and costs.

### **ARGUMENT**

### I. THE SUBPOENA IS UNTIMELY AND THUS PER SE UNDULY BURDENSOME.

Rule 45 subpoenas issued to nonparties are fact discovery and thus must be issued during the fact discovery period. *See* Mem. in Supp. of Mot. to Quash at 8–10, ECF No. 2 (hereafter, "Mem."). AII concedes (as it must) that the court-ordered schedule in *Gref* set the close of fact discovery in November 2021. Opp. to Mot. to Quash at 7, ECF No. 4 (hereafter, "Opp.") (citing Opp. Ex. O, ECF No. 4-15). The Subpoena therefore is untimely and should not have been issued.

Notably, AII offers no explanation for why it did not issue the Subpoena during fact discovery, despite having been well familiar with Dr. Emory and the Article since *Gref* was filed,

if not earlier. See Mem. 9–10 & Ex. 2, Emory Decl. ¶ 8, ECF No. 2-2 (explaining that AII has been aware of the Article since at least September 2020). All does not even attempt to address this point. Instead, AII tries to muddy the waters by arguing that some scattershot discovery was completed after the fact discovery deadline, and that this shows that discovery is "ongoing." See Opp. 10–11. But absent from AII's brief and its thirty-six exhibits is any citation to a court order extending fact discovery past November 2021. This should be dispositive. That the *Gref* parties may have reached agreement to allow certain, limited party discovery past the discovery cutoff does not supersede court-ordered discovery deadlines, nor give AII license to issue a nonparty subpoena outside the discovery period. Moreover, virtually all of the "ongoing" discovery AII points to was completed many months ago and involves either a deposition of a witness central to the case, such as a treating physician, or narrow written discovery requests among the parties. See Opp. 7–8. And while AII claims "multiple" fact discovery issues are outstanding, Opp. 10, it identifies just one, id. at 8—a subpoena issued many months ago (and apparently recently re-issued due to a service defect). See Ex. 2, Def.'s Ltr., *Gref*, No. 1:20-cv-5589 (S.D.N.Y. Dec. 2, 2022), ECF No. 287. That is a slender reed on which to base an argument that discovery writ large remains open.

Nor can AII circumvent its timeliness problem by arguing that the Subpoena is expert discovery. As a threshold matter, under the operative court order, expert discovery closed on July 29. See Opp. 7. A few stray expert depositions have been continued past that deadline in response to joint requests by the *Gref* parties, but in each instance the parties' requests for additional time were limited to expert *depositions*, and the *Gref* court has never more broadly extended the expert discovery deadline.<sup>2</sup> Indeed, that the *Gref* parties (including AII) felt the need to repeatedly ask

<sup>&</sup>lt;sup>2</sup> See Opp. Ex. Q, ECF No. 4-17 (representing that "[t]he case remains on schedule," with the "one exception" being "completion of expert depositions" and requesting "through July 29, 2022 to complete expert depositions"); Opp. Ex. R, ECF No. 4-18 (making a "joint request for an extension

the court for additional time to complete expert depositions shows they understood that discovery was closed and court permission was required to proceed. Thus, even if AII could somehow claim the Subpoena is expert discovery—it is not—it still is untimely because no one affiliated with Peninsula is an expert in *Gref*, nor does the Subpoena seek the deposition of an expert.<sup>3</sup>

AII claims that the purpose of scheduling orders is simply to "alleviate attempts to reopen discovery on the eve of trial," and that because no trial date has been set, this Court need not be concerned about permitting this discovery after the discovery cutoff. Opp. 10. This is flat wrong. "Deadlines exist in order to move litigation along," and '[a] scheduling order is not a frivolous piece of paper, idly entered, which can be cavalierly disregarded by counsel without peril." *Ball v. Takeda Pharms. Am., Inc.*, 963 F. Supp. 2d 497, 509 (E.D. Va. 2013) (citation omitted). Rule 16(b) "requires district courts to enter scheduling orders that limit the parties' time to complete discovery," which "shall not be modified except upon a showing of good cause' and only by leave of the district judge." *McKay v. Triborough Bridge & Tunnel Auth.*, No. 05 Civ. 8936, 2007 WL 3275918, at \*1 (S.D.N.Y. Nov. 5, 2007). AII's sole citation for its contrary argument is a nearly thirty-year-old out-of-circuit decision, which only undermines their argument. In *Buhrmaster v. Overnite Transp. Co.*, 61 F.3d 461 (6th Cir. 1995), the court affirmed a decision to quash a subpoena issued after fact discovery where the issuing party "had adequate opportunity to discover

by which to complete expert depositions" to October 7, 2022 and representing that "[t]he parties continue to move forward diligently according to the current deadlines but are in need of additional time to coordinate cover and the logistics presented by the multitude of expert depositions"). Further, while AII cites the *Gref* court's September 6 order adjourning the pretrial conference "until discovery is completed," Opp. 7, 10, this order did not extend discovery, but rather simply postponed the conference to allow ongoing expert depositions to be completed.

<sup>&</sup>lt;sup>3</sup> Moreover, Mr. Gref's experts cited dozens of studies and barely address Dr. Emory's study. *See infra* § II.A. No reasonable understanding of the scope of expert discovery could permit nonparty subpoenas after the fact discovery cutoff simply because an expert happened to cite their research.

this material" during discovery. *Id.* at 464. The same result should apply here.

Second, AII claims that the "subpoena [is] timely" because it "does not violate any scheduling orders of this Court." Opp. 11. This hardly deserves a response. Rule 45 required that Peninsula file its motion in this Court, "where compliance is required." Had Peninsula moved to quash in the Gref litigation, its motion would have been denied for lack of jurisdiction. See, e.g., In re Smerling Litig., No. 21 Civ. 2552, 2022 WL 684148, at \*2 (S.D.N.Y. Mar. 8, 2022) ("issuing court lacks 'jurisdiction over'" motions to quash, which must be filed "where compliance is required"). It cannot be that Peninsula is simply powerless to quash an untimely subpoena. AII cites just one distinguishable decision to support its claim that "[n]umerous" courts have rejected attempts by third parties to quash untimely subpoenas. In Somaxon Pharms., Inc. v. Actavis Elizabeth LLC, a party to the underlying litigation moved to quash a subpoena issued to a third party, and the court ruled that it lacked standing do so, even on timeliness grounds. No. 22 Misc. 162, 2022 WL 3577904, at \*3 (S.D.N.Y. Aug. 18, 2022). When a subpoena should not have been issued, literally everything done in response to it constitutes an undue burden[.]" Builders Ass'n of Greater Chicago v. City of Chicago, No. 96 C 1122, 2002 WL 1008455, at \*4 (N.D. III. May 13, 2002). AII's untimely Subpoena should not have been issued and thus imposes a per se undue burden, and this Court accordingly not only has authority to quash the Subpoena, it must do so.

### II. THE SUBPOENA SEEKS IRRELEVANT AND BURDENSOME INFORMATION.

Even if the Court were to look past AII's delay in serving the Subpoena—which it should not—Rule 45(d)(3)(A)(iv) requires quashing the Subpoena. Because Peninsula is a nonparty, the Court must make a particularly "demanding" analysis of whether AII's supposed need outweighs

<sup>&</sup>lt;sup>4</sup> AII's effort to distinguish Peninsula's cited cases, Opp. 11 & n.6, likewise fails. That the court where the underlying litigation is pending may also reject a subpoena issued after the close of discovery does nothing to show that this Court cannot quash a subpoena on timeliness grounds.

the burdens the Subpoena imposes. *Virginia Dep't of Corr. v. Jordan*, 921 F.3d 180, 189 (4th Cir. 2019). AII—not Peninsula—bears the "burden of demonstrating [] relevance." *Citizens Union of City of New York v. Att'y Gen. of New York*, 269 F. Supp. 3d 124, 148 (S.D.N.Y. 2017). It has not carried that burden, nor has it come close to showing that its need for what is at best marginally relevant discovery outweighs the immense burdens on Peninsula.

### A. AII Has Not Satisfied Its Burden To Show Relevance Or Need.

It is undisputed that neither Dr. Emory nor Dr. Maddox—nor anyone else affiliated with Peninsula—is involved in the *Gref* litigation in any way. Emory Decl. 9, ECF No. 2-2; Maddox Decl. 5, ECF No. 2-3; Smith Decl. 7, ECF No. 2-1. Yet AII claims the requested information is "critical to its defense" because two of Mr. Gref's experts, Dr. Moline and Dr. Finkelstein, "rely on" the Article to support their opinions that cosmetic talc caused his mesothelioma. Opp. 5, 12. AII vastly overstates the relevance of the Article. This is not a case where the relevant expert's opinions are based "exclusively on" a subpoenaed third-party's publications, such that quashing those subpoenas would "effectively preclude[] [defendant] from engaging in any meaningful cross-examination" of the plaintiff's experts. *Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 562 (7th Cir. 1984). *See also id.* at 558 (noting "[a]ll parties agree that" subpoenaed doctor's research was "of enormous significance" because it was the first to identify a link between relevant toxin and disease). On the contrary, Dr. Moline and Dr. Finkelstein cite the Article only in passing:

<sup>&</sup>lt;sup>5</sup> AII claims "PPA employs inconsistent phrasing to discuss members, partners, employees/staff," and queries "whether this is intentional." Opp. 3 n.1. Peninsula did not use the term "partner" in its briefing. And, as Peninsula stated, Dr. Emory is a Peninsula officer, and Dr. Maddox is a parttime Peninsula employee. Mem. 1 & Emory Decl. ¶¶ 2, 6, ECF No. 2-2. AII does not explain what supposed inconsistency it is referring to, or why this bears on this Court's analysis.

<sup>&</sup>lt;sup>6</sup> Reilly v. Pinkus, 338 U.S. 269 (1949) also does not support AII's arguments. To start, AII wrongly attributes a quote from *Deitchman* to *Reilly*. Compare Opp. 14 with Deitchman, 740 F.2d at 562 ("Although the scope of cross examination . . ."). Reilly instead raised concerns where the trial court prohibited any cross-examination about medical literature that contradicted the

- **Dr. Moline** relies on *492 publications* to support her opinions. Moline Report, Opp. Ex. H at 57–83, ECF No. 4-8. She discusses the Article in a single sentence, as one of many sources generally discussing asbestos exposure from cosmetic talc. *Id.* at 22. Dr. Moline does not even reference (much less rely on) the Article to support her conclusion that Mr. Gref's mesothelioma was caused by his exposure to any particular products produced by any defendant. *See id.* at 23–24.
- **Dr. Finkelstein** also relies on hundreds of publications, and devotes a mere half page of his 292-page report to the Article, where it is referenced in a section titled "Human Health Effects of Talc Exposure" and discussed among dozens of other sources. Finkelstein Report, Opp. Ex. I at 233, ECF No. 4-9. *See also generally id.* at 213–64.

Under AII's theory of relevance, any third-party researcher could be subjected to intrusive discovery of both their source data—even if ethical considerations bar its disclosure—and internal financial records (that have no bearing on whether cosmetic talc caused Mr. Gref's mesothelioma) merely because some litigation expert cited to a study as one of many supporting their opinions.<sup>7</sup> That is not the law, and the Court must tread cautiously atop that slippery slope.

It makes no difference that AII wishes to attack Dr. Moline's study by speculating about potential overlap among the human subjects in her study and the Article. Opp. 13. AII remains free to depose and cross-examine Dr. Moline about the accuracy of facts and assumptions underlying the opinions she has advanced on behalf of Mr. Gref, including the Article and the other hundreds of publications she relies on. That AII apparently chose not to pursue this course—barely mentioning the Article when deposing Drs. Moline and Finkelstein—undermines AII's claim of relevance and certainly is not a reason to subject Peninsula to AII's intrusive requests now.<sup>8</sup>

testifying expert's opinions, such that the challenging party was functionally "deprive[d] . . . of all opportunity to interrogate [the expert] about divergent opinions." 338 U.S. at 275.

<sup>&</sup>lt;sup>7</sup> As explained *infra* § II.B, AII also never explains how Peninsula's financial records are relevant to their quest to show that study subjects were not "exposed only to cosmetic talc." Opp. 13.

<sup>&</sup>lt;sup>8</sup> See Ex. 3, Dep. of Dr. Jacqueline Moline, MD, Gref, Sept. 23, 2022 (never mentioning the Article); Ex. 4, Dep. of Dr. Jacqueline Moline, MD at 141:15–145:3, Gref, July 6, 2022 (briefly discussing Dr. Emory's article); Ex. 5, Dep. of Dr. Murray M. Finkelstein, MD at 67:21–68:16, Gref, June 22, 2022 (same). To minimize the burden on the Court given the already voluminous record on this Motion, Peninsula has attached only the cited excerpts of these transcripts, but would

Further, as Peninsula previously noted (an argument AII ignores), nothing prohibits AII from presenting its own experts to try to undermine Mr. Gref's experts or the Article. Mem. 12–13 (citing *Rosa v. City of Seaside*, No. 05-03577, 2009 WL 2382760, \*2 (N.D. Cal. July 29, 2009)).

AII also overstates the Article's relevance by describing its "central premise" as stating that "cosmetic talc caused more than 100 mesotheliomas in the study subjects (i.e., plaintiffs) combined with those in" Dr. Moline's study. Opp. 13. The Article nowhere makes that claim. Instead, it reports that "findings of the present and other recent studies suggest that cosmetic talc *may be a cause* of malignant mesothelioma," and that "[l]arge-scale controlled studies will be required to assess the prospective risk of developing mesothelioma following repeated exposures to talc." Article, ECF 2-2 at 11. The authors reiterated this point in a subsequent response to criticism of the Article, where they also noted that it is "only one piece of ever-growing evidence, including the conclusion by the [World Health Organization's International Agency for Research on Cancer], that this is the case." Ex. 6, Supplemental Declaration of Dr. Theresa S. Emory, MD ¶ 3, Attach. A (collecting sources) (hereafter, "Emory Supp. Decl.").

That AII waited until a year after fact discovery closed to even seek this discovery from Peninsula further undermines AII's relevance arguments and undercuts any claimed "need" for the information. *See* Mem. 13–14; *Amini Innovation Corp. v. McFerran Home Furnishings, Inc.*, 300 F.R.D. 406, 411 (C.D. Cal. 2014) (delay in seeking discovery undermines relevance). AII does not even bother to respond to Peninsula's argument on this point—an omission that is striking but not surprising since AII has indisputably been aware of the Article at least since *Gref* was filed.

Nor should the Court give any weight to AII's circular argument that the Subpoena is appropriate because AII has been unable to obtain the exact information it now seeks through other

be happy to provide full copies at the Court's request.

means. That courts have barred AII's inquiry into these subjects is a reason to grant this Motion, not deny it. *See infra* § III. In any case, the relevant inquiry is whether AII cannot obtain "comparable information" from other sources. *Jordan*, 921 F.3d at 189. AII has had ample opportunities to do just that through depositions of Dr. Emory or Dr. Maddox in other cases, Opp. 15, depositions of Mr. Gref's experts, and development of their own experts' opinions.

### B. The Subpoena Is Unduly Burdensome, For Multiple Reasons.

Under the "more demanding variant of the proportionality analysis" applicable to nonparty subpoenas, the Court must determine whether AII's purported need for the discovery outweighs the burden on Peninsula. *Jordan*, 921 F.3d at 189. This inquiry encompasses far more than the "costs of compliance." *Id.* at 189–90 & n.3 (recognizing many "cognizable burdens" beyond "dollar-and-cents costs associated with a large and demanding document production"). Peninsula has identified several significant burdens, each of which outweighs AII's attenuated claim of need.

**Nonparty status.** AII's argument that because Peninsula is involved in litigation as a general matter, the Court can disregard its nonparty status in assessing burden is incorrect and based on AII's misquotation of controlling precedent. In *Jordan*, the Fourth Circuit held that because "[n]onparties are 'strangers' to *the litigation*" at issue, they are entitled to greater

<sup>&</sup>lt;sup>9</sup> None of the cases cited by AII provides otherwise. *See Sheet Metal Workers Int'l Ass'n v. Sweeney*, 29 F.3d 120, 125 (4th Cir. 1994) (discussing burden imposed on party asserting *attorney-client privilege*); *In re: Mod. Plastics Corp.*, 890 F.3d 244, 251–52 (6th Cir. 2018) (affirming sanctions for unduly burdensome subpoenas, and noting that burden is "assessed in a case-specific manner"); *Citizens Union of City of New York*, 269 F. Supp. 3d at 148 (quashing subpoena where requesting party "failed to meet their burden of demonstrating" relevance); *Ohio Valley Env't Coal., Inc. v. U.S. Army Corps of Engineers*, No. 1:11MC35, 2012 WL 112325, at \*3 (N.D. W. Va. Jan. 12, 2012) (modifying subpoena where "sole arguments" on burden concerned cost and time); *Convertino v. U.S. Dep't of Just.*, 565 F. Supp. 2d 10, 14 (D.D.C. 2008) (dismissing a *party's* generalized undue burden objections to *document requests* absent any support for the objection); *Cory v. Aztec Steel Bldg., Inc.*, 225 F.R.D. 667, 672 (D. Kan. 2005) (same, where objecting party's only basis for burden objection was that compliance would require "numerous man hours").

protection from burden. 921 F.3d at 189 (emphasis added). AII's brief purports to quote *Jordan* but omits the article "the," which changes the meaning of the sentence entirely. Opp. 16. It bears noting that the party claiming burden in *Jordan* was the Commonwealth of Virginia, which (obviously) is not a "stranger to litigation" generally (but was a "stranger" to the litigation there at issue). Here, the fact that members of Peninsula's practice have provided litigation consulting services in other lawsuits does nothing to change Peninsula's status as a nonparty in *Gref*, or its entitlement to the additional protections that status affords. <sup>10</sup> *See* Mem. 11–12.

Overbreadth. The Subpoena also seeks information far beyond what AII claims is relevant to its case. As discussed above, AII claims the requested information is necessary to "allow for cross-examination of plaintiff's experts on the data underling [sic] their opinions." Opp. 13. But the Subpoena does not merely seek the data examined in the Article—it also seeks Peninsula's financial records and billing documents relating to other litigations not at issue here. *See* Subpoena Request Nos. 1(i), 4, 7, 8, 10, 11. These invasive requests have nothing to do with the "critical issue" AII highlights: "[w]hether cosmetic tale causes mesothelioma." Opp. 13. At most, they may relate to a collateral attack on a third-party researcher's bias, which is a dubious basis for relevance and also disclosed in the Article itself. *See* Article, ECF No. 2-2 at 9, 11 (noting that the underlying "cases were submitted in medico-legal consultation, all of which potentially introduce bias" and disclosing that the authors "have testified in asbestos litigation, primarily for plaintiffs").

Chilling effect. There is ample authority—much of which AII ignores, *compare* Mem. 12–

<sup>&</sup>lt;sup>10</sup> AII complains that Peninsula "does not state" whether Mr. Gref was one of the subjects of the Article, Opp. 16 n.7. For all the reasons discussed herein, *see infra* § III, it would be inappropriate to de-anonymize the subjects to determine and reveal whether Mr. Gref was among the seventy-five cases examined. But as AII is aware, the Article lists only two cases where the relevant diagnosis was made in 2019—as Mr. Gref's was, *see* Moline Report, Opp. Ex. H at 6, ECF No. 4-8—and these subjects' age at diagnosis (73 and 71 years old) exceed Mr. Gref's (36 years old). *Compare* Moline Report, Opp. Ex. H at 4, 6, ECF No. 4-8 *with* Article, ECF No. 2-2 at 8–9.

13 & n.4 with Opp. 16–17—describing the undue burden imposed by subpoenas that seek the data underlying third-party researchers' publications. In just one such example, a court quashed a subpoena issued to a third-party researcher based on the "serious danger" created by "permitting discovery in these situations," which "inevitably tend[] to check the ardor and fearlessness of scholars." *In re Fosamax Prod. Liab. Litig.*, No. 1:06-MD-1789, 2009 WL 2395899, at \*4 (S.D.N.Y. Aug. 4, 2009). Many other courts have recognized that "[c]ompelled disclosure of confidential information" like that sought here would "severely stifle research into questions of public policy, the very subjects in which the public interest is greatest." *Richards of Rockford, Inc. v. Pac. Gas & Elec. Co.*, 71 F.R.D. 388, 390 (N.D. Cal. 1976) (denying motion to compel third-party testimony and document production related to confidential research subjects).

That the subjects of the study were not aware of (and so did not consent to) their participation does not lessen these concerns, as AII suggests. Opp. 16–17. As Dr. Emory has explained, it is challenging to research rare diseases like mesothelioma because it is difficult to identify a sufficient sample of cases to study. *See* Emory Supp. Decl. ¶ 10. Most patients who are diagnosed with mesothelioma, however, end up pursuing litigation related to that diagnosis. *Id.* If researchers like Dr. Emory are subjected to burdensome subpoenas such as this in lawsuits across the country—even where they are simply a nonparty who published a study—it would significantly chill their ability and willingness to research this exceedingly rare and lethal disease, and assist medical advancements related to its treatment. *Id.* 

Invasion of privacy. A closely related burden—discussed at length below, see infra § III—is that the Subpoena threatens to invade serious "confidentiality interests." *Jordan*, 921 F.3d at 189. See also In re: Mod. Plastics Corp., 890 F.3d at 251–52 (quashing subpoena "implicat[ing] significant concerns about customer privacy"). AII seeks to dismantle widely accepted,

longstanding principles of medical ethics that prohibit the Article's authors from revealing the human subjects' identity. *See infra* § III; Mem. 15–18. This burden should not be taken lightly, particularly given Dr. Emory's concerns that revealing this information would violate medical ethics rules and could jeopardize her medical license. Emory Decl. ¶ 10, ECF No. 2-2.

Time and expense. Finally, Dr. Emory's supplemental declaration paints a clear picture of the significant time and expense that Peninsula and Dr. Emory would face if forced to respond to the Subpoena. Dr. Emory maintains a full-time medical practice, serving upwards of 100 patients per day. Emory Supp. Decl. 4. She typically devotes at least ten hours per day to patient care. *Id.* Dr. Emory's medical-legal consultation services account for less than 10% of her professional duties, and a small share of her overall income. *Id.* 5. And because Dr. Maddox is retired and works only part-time, the entire burden of responding to the Subpoena would fall on Dr. Emory. *Id.* 6. She has no staff that assists her with medical-legal consultation work, nor would she have any assistance collecting or reviewing the materials the Subpoena seeks. *Id.* Dr. Emory's best estimate is that she would need to divert hundreds—if not thousands—of hours away from patient care and her medical practice to respond to the Subpoena, which may require Peninsula to hire a contract pathologist to assist with patient care. *Id.* 7. These burdens are real, they are significant, and they far outweigh AII's manufactured need for this irrelevant information.

### III. THE SUBPOENA SEEKS PRIVILEGED OR OTHER PROTECTED MATTER.

In addition to being untimely, irrelevant, and unduly burdensome, the Subpoena also improperly seeks to compel the production of protected material, which is an independent basis to

This supplemental declaration responds to AII's suggestion that Peninsula made only "conclusory and unsubstantiated" burden arguments, Opp. 15, and expands on Dr. Smith's earlier declaration, which attested that compliance would be "burdensome and costly," and "divert time and resources from Peninsula's busy medical practice." Smith Decl. ¶ 6, ECF No. 2-1.

quash it.<sup>12</sup> AII devotes a third of its brief to this question, but does not cite a single case where a court has permitted the intrusive discovery it seeks—let alone from a nonparty whose only connection to the litigation is that two experts in the underlying case apparently cite Dr. Emory's study (among literally hundreds of others). That should tell the Court all it needs to know.

### A. The Subpoena Improperly Seeks Protected Material.

Subpoena Request Nos. 1–3, 5, 6, 9, and 12–18 ask Peninsula to reveal the identities and other sensitive medical information of the 75 human subjects discussed in the Article. This information has never been disclosed, and courts have uniformly shut down attempts by AII and others to gain access to it. *See* Mem. 16 & n.6 and *infra* at 16–17. AII responds that the information is not protected because (i) it "was obtained from plaintiffs' lawyers" and therefore was "litigation-driven," (ii) "[a]ll 75 subjects publicly placed their medical condition at issue by filing lawsuits," and (iii) Peninsula, Dr. Emory, and Dr. Maddox "profited handsomely from medical-legal consulting." Opp. 18–19. All three arguments are wrong on both the facts and the law.

First, the facts. As Dr. Emory has attested under oath, her sole aim in writing the Article—which was published in a respected, peer-reviewed journal—was to educate the public and medical community about mesothelioma. Emory Supp. Decl. ¶ 9. While AII emphasizes that the study's subjects were first identified through their participation in litigation relating to their mesothelioma diagnoses, that is neither relevant nor notable. As Dr. Emory has explained, it would be "virtually

<sup>&</sup>lt;sup>12</sup> AII's arguments in Section III of its brief rely on the wrong provision of Rule 45. Rule 45(d)(3) governs motions to quash. The relevant sub-provision here is Rule 45(d)(3)(A)(iii), which mandates that a court "must quash" a subpoena that seeks "privileged or other protected matter" where "no exception or waiver applies." For the reasons explained in Peninsula's brief, Mem. 15–18, and *infra* § III.A, that standard is satisfied. AII does not address Rule 45(d)(3) at all; its sole citation to that provision is a passing reference in its legal standard section. It instead relies entirely on Rule 45(e)(2), Opp. 17–18, 24–25, which has no application to this Motion. For similar reasons, AII's arguments applying the Rule 26(c) standard for a protective order, Opp. 17–18—rather than the Rule 45(d) standard for a motion to quash—miss the mark.

impossible" to study mesothelioma—or make medical advancements related to its treatment—if researchers were chilled from conducting studies that relied on litigation files. Emory Supp. Decl. ¶ 10; *supra* § II.B (discussing why this also imposes an undue burden). AII's argument that the Article is "litigation-driven" (read: biased) is baseless, and the Court should reject it. <sup>13</sup>

AII's next argument that the subjects of the study "publicly placed their medical condition at issue by filing lawsuits," and that it therefore "is inaccurate to argue that the[ir] identities have never been revealed," Opp. 18, 23, likewise is wrong. As the Article itself explains, 140 subjects "with documented exposures to cosmetic talc were initially reviewed" for potential inclusion in the study. Article, ECF No. 2-2 at 7. Ultimately, 65 of the initial 140 subjects were excluded because of other known exposures to asbestos (unrelated to cosmetic talc), leaving 75 subjects in the study. *Id.* The subjects were anonymized and their identities have never been disclosed, including to the subjects themselves. <sup>14</sup> Nor can AII seriously contend that by filing lawsuits, the plaintiffs in these litigations consented to broad disclosure of their medical files outside of their own individual cases. As discussed below, this argument has been uniformly rejected.

AII's final contention that because Dr. Emory and Dr. Maddox have been engaged as paid experts in other talc litigation, the identities and private health information of anonymous research

<sup>&</sup>lt;sup>13</sup> Of course, nothing prevents AII from endeavoring to attack Dr. Emory's credibility in cases where she is an expert. And AII has made aggressive efforts to do so, including by deposing her *for 24 hours* about the Article in one talc case where she was a testifying expert. *See* Mem. 10.

<sup>&</sup>lt;sup>14</sup> AII's claim that Dr. Emory "has freely provided information" about one of the study subjects "with another prominent plaintiff's expert." Opp. 23, is incorrect and misleading. As the exhibit AII cites shows (Opp. Ex. EE, ECF No. 4-31), Dr. Emory did not reveal any identifying information about the subject at issue. Rather, she provided only the name of the product the subject had been exposed to, which is not confidential or sensitive, and which is routinely included in scientific publications. In fact, as Dr. Emory has attested, among the reasons she and her coauthors chose not to include the names of the products to which the subjects of the study had been exposed was precisely because the study was not some attempt to spawn or bolster litigation, but rather focused on patient care and treatment as a general matter. Emory Supp. Decl. ¶ 9.

subjects are somehow less deserving of protection, Opp. 18, 20 n.9, is both nonsensical and offensive. That a physician who conducts research may sometimes be engaged as a litigation expert cannot possibly be a basis to require that they open their confidential research files and financial records to defense counsel in cases that they have no connection to. *See also supra* § II (discussing lack of relevance of Peninsula's financial and billing records).

AII's arguments also fail as a matter of law. To start, Peninsula has not invoked and does not rely on the so-called "Common Rule" as the basis of its Motion, so AII's argument on this front, Opp. 19–21, is entirely inapposite. Peninsula's argument is instead that the information should be protected from disclosure because it concerns the confidential, private information of human research subjects, which courts routinely shield from disclosure based on general principles of medical ethics and the need to avoid chilling important medical and scientific research. See Mem. 15–16 (citing cases, none of which relied on the Common Rule as the basis for protection). See also Emory Decl. ¶ 10, ECF No. 2-2 (attesting that Dr. Emory is bound by medical ethics to maintain the confidentiality of the study subjects and that disclosing the information could jeopardize her medical license); supra § II.B (discussing the related undue burden these requests impose). AII claims that these principles and protections do not apply to studies where the subjects were identified through litigation. Opp. 21. AII offers no authority supporting this proposition, and its attempts to distinguish Peninsula's cited cases, id. at 21 n.10, fail. For example, AII contends that Andrews, Doe, and In re Fosamax are distinguishable because the subjects there were assured that their sensitive information would remain confidential. Opp. 21 n.10. So too here—any authorizations the study subjects may have made in their own individual litigations were strictly

<sup>&</sup>lt;sup>15</sup> Further, as another recent filing in *Gref* demonstrates, AII's own experts agree that the identities of human subjects are protected under HIPAA, as well as other laws and ethical rules. *See* Ex. 7, Pl.'s Ltr., *Gref*, No. 1:20-cv-5589 (S.D.N.Y. Dec. 7, 2022), ECF No. 289.

limited to their individual cases. *See infra* at 16–18; Emory Supp. Decl. ¶ 11. That leaves *Lampshire* and *Farnsworth*, where AII's own parenthetical descriptions show that the courts required redactions of all identifying or personal information. <sup>16</sup> Opp. 21 n.10.

Moreover, as Peninsula's opening brief pointed out, courts in other recent cosmetic talc litigation have uniformly rejected AII's identical attempts to elicit the identities of research subjects—even when the studies at issue were conducted by testifying experts in those cases. Mem. 16 & n.6. In Bell, for example, the court expressly rejected AII's efforts to identify human subjects, "even if it is based on litigation study" because "the fact that those individuals may have consented in their own case does not mean that they've consented to some broader identification or disclosure." Ex. 8, Hr'g Tr. at 73:2–9, Bell v. Am. Int'l Indus., No. 1:17-cv-111 (M.D.N.C. Sept. 25, 2020) (hereafter, "Bell Tr."). The Bell court further explained: "I don't see a basis for requiring disclosure, and I don't see any case law that would support that as far as other [non-named plaintiff] individuals who may have been included in the study." Id. at 73:17–19. In Johnson/Lashley, the court likewise rejected AII's attempt (represented by the same counsel as here) to reveal the identities of subjects in another talc study. See Ex. 9, Trial Tr. at 220:1–221:5, 225:25–226:7, Johnson/Lashley v. Am. Int'l Indus., Nos. MID-L-006651-16 and MID-L-007336-16 (N.J. Super. Ct. Law Div. Mar. 11, 2020) (admonishing AII for attempting to disclose identities of study subjects as "inappropriate" and "improper," and sustaining several objections to questioning on that topic). And in Fisher, the court likewise sustained repeated objections to AII's attempts (again

<sup>&</sup>lt;sup>16</sup> AII does not address *Richards*, 71 F.R.D. 388, which Peninsula also cited. Mem. 16. *Richards* involved a subpoena issued to a nonparty researcher who refused to disclose the identities of study subjects on privacy grounds. The court denied a motion to compel, explaining that society's "profound interest" in research—which is often facilitated through confidential information-gathering—"far outweigh[ed]" the private litigant and public's interests in "the fair and efficient resolution of civil disputes in courts of law." *Richards*, 71 F.R.D. at 389–91.

represented by the same counsel as here) to reveal this information during cross-examination of one of the plaintiff's experts. <sup>17</sup> See Ex. 10, Trial Tr. at 39:17–45:4, Fisher v. Am. Int'l Indus., No. 19070087 (Pa. C.P. Oct. 13, 2022).

AII was a party to both Johnson/Lashley and Fisher—which address the precise issue before the court, see Mem. 16 & n.6—yet AII's brief does not even acknowledge these decisions. AII does address *Bell*, which it badly mischaracterizes. Opp. 22. In that case—where Dr. Emory was a testifying expert—the court again rejected AII's attempt to unmask research subjects. See Bell v. Am. Int'l Indus., No. 1:17-cv-111, 2022 WL 16571057, at \*11 (M.D.N.C. Sept. 13, 2022). The sole exception concerned the named plaintiff, who was "deceased by the time the study began," and who the court thus determined never qualified as a confidential "human subject." Id. The Bell court also clarified that its ruling did not apply to any of the other study subjects. Id. (deeming it "critical" that the proposed disclosure "redacts all information on other" subjects). See also Bell Tr. at 8:3–9, 8:17–21, 67:12–68:13 (noting that disclosure of human subjects other than Ms. Bell presented a "very different issue"); id. at 61:3–13 (expressing "complete[] agree[ment]" with the ruling in *Johnson/Lashley* that it would be improper to identify any human subjects other than the plaintiff). Thus, Bell actually undermines AII's arguments. The same is true of Andrews v. E.R. Squibb & Sons, Inc., 97 F.R.D. 494 (N.D. III. 1983), the only other case AII cites. Opp. 21– 22. As in Bell, the Andrews court limited disclosure to information concerning the individual plaintiffs in that suit—who had "freely disclosed all of their relevant medical records" without asserting "confidential[ity]" or any other "privilege[]," 97 F.R.D. at 504—while otherwise rejecting the defendant's attempts to reveal the identities of other subjects, id. at 499.

<sup>&</sup>lt;sup>17</sup> Several other courts have ruled accordingly on this exact issue in recent months. *See* Ex. 1, *Gref* Ltr. at 9–15 (discussing decisions in *Harpster v. Chanel, Inc., Stanley v. Avon Products, Inc., et al.*, and *Zimmerman v. Autozone, Inc., et al.* protecting talc study human subject information).

Finally, AII's HIPAA argument is a red herring. AII claims—without citation to any authority—that because the Article's subjects "placed their medical conditions at issue" by filing lawsuits related to their mesothelioma diagnoses, they waived any HIPAA protections. Opp. 23– 24. This is simply wrong. As Dr. Emory attests, plaintiffs who file litigation related to their mesothelioma diagnoses typically execute *limited* HIPAA authorizations permitting disclosure of their medical records only in the specific litigation in which they are a plaintiff. Emory Supp. Decl. ¶ 11. These authorizations thus do not effectuate some broad waiver of HIPAA protections or permit use of sensitive health information outside the confines of individual litigations. *Id. Bell* is once again instructive. There, the court noted that while defense counsel could "use the [HIPAA] authorization that Ms. Bell had agreed to in this case . . . it would be very different if defense counsel had used Ms. Bell's authorization from this case to obtain the release of information in some other case." Ex. 8, Bell Tr. at 8:12-17; see also id. at 8:18-21 (noting "important confidentiality and privacy issues" preventing discovery of study subjects outside of their own litigations); id. at 73:2–9 (that study subjects consented to disclosures "in their own case does not mean they've consented to some broader identification or disclosure").

# B. No Privilege Log Is Required In These Circumstances.

AII's argument that Peninsula waived any argument on the grounds of "privilege or other protection" because it did not create a privilege log, Opp. 24–25, is wrong. Where, as here, a party moves to quash a subpoena in its entirety based on a *categorical* protection, courts routinely hold that a privilege log is not required. *See, e.g., Jordan v. Comm'r, Mississippi Dep't of Corr.*, 947 F.3d 1322, 1328 & n.3 (11th Cir. 2020), *cert. denied sub nom. Jordan v. Georgia Dep't of Corr.*, 141 S. Ct. 251 (2020) (where respondent sought to quash entire subpoena based on statutory privilege, no privilege log was required); *Chestnut v. Kincaid*, No. CV 20-2342, 2022 WL 350117,

at \*3 (D. Md. Feb. 4, 2022) (where respondent moved to quash entire subpoena on First Amendment grounds, refusal to provide privilege log "did not constitute a waiver"); *Livingston v. Kehagias*, No. 5:16-CV-906, 2018 WL 1278190, at \*2–3 (E.D.N.C. Mar. 12, 2018) (finding "no need" for privilege log where respondent moved to quash entire subpoena).

This makes sense. "The purpose of a privilege log is to enable the parties to assess [a] claim of privilege," *Jordan*, 947 F.3d at 1328 n.3 (cleaned up), by providing information about, for example, who was privy to a communication. Here, "it is apparent from the face of the subpoena," that the information sought *categorically* falls within the claimed protection, *see* Mem. 15–18, *supra* § III.A, so a privilege log would be pointless. 18 *Jordan*, 947 F.3d at 1328 n.3; *see also W. Coast Invs., LLC v. D.R. Horton, Inc.*, No. 19-14360-CIV, 2020 WL 3088962, at \*2 (S.D. Fla. Mar. 12, 2020) (finding "no practical need for a privilege log" where respondent asserted privilege over "entire file"). The cases AII cites, Opp. 24–25, are not to the contrary. Both simply recite the general principle—undisputed but also inapplicable here—that a party seeking to withhold select documents must furnish a privilege log. *In re Grand Jury Subpoena*, 274 F.3d 563 (1st Cir. 2001); *Dorf & Stanton Commc'ns., Inc. v. Molson Breweries*, 100 F.3d 919 (Fed. Cir. 1996).

### IV. SANCTIONS ARE WARRANTED.

Rule 45(d)(1) is clear: a party "serving a subpoena *must* take reasonable steps to avoid imposing undue burden or expense" on a third-party recipient. And where a party fails to do so, the court "*must* . . . impose an appropriate sanction." Fed. R. Civ. P. 45(d)(1) (emphases added). AII's untimely, overbroad Subpoena seeks irrelevant, far-reaching, and clearly protected information, *see* Mem. 10–18; *supra* §§ I-III, and AII has taken no steps—much less reasonable

<sup>&</sup>lt;sup>18</sup> AII submits that Peninsula should be required to produce a privilege log to "allow it and the Court the opportunity to assess the veracity of the alleged protections." Opp. 25 n.11. But nowhere in the lengthy section of its brief arguing the privilege issue does AII ever actually complain that it lacks information needed to make this assessment or rebut Peninsula's claim of privilege.

ones—to avoid unduly burdening Peninsula.

AII hardly responds to Peninsula's sanctions argument, and its only argument—that Peninsula must show "bad faith" to merit sanctions, Opp. 25 n.12—is wrong on the law, as one of AII's own cited cases confirms. *In re: Mod. Plastics Corp.*, 890 F.3d at 251–52 (affirming award of attorney's fees and costs as sanctions under Rule 45 without regard to bad faith). *See also* Mem. 19–21 (collecting cases confirming a showing of bad faith is not required). AII does not even bother to address the many cases that support Peninsula's position on this issue, much less the cases that mandate sanctions here. *Compare* Opp. 25–26 *with* Mem. 19–21.<sup>19</sup>

Even worse, AII also completely ignores (or rather, avoids) the facts. Counsel for Peninsula asked AII to withdraw the Subpoena after AII's counsel failed to cite a single discovery order to support their view that fact discovery remains open. Mem. 19–20. They still have not done so. *See supra* § I. And we now know that AII also refused to respond to Mr. Gref's attempts to meet and confer regarding the Subpoena and their position that it was untimely. Pl.'s Ltr., *Gref*, No. 1:20-cv-5589 (S.D.N.Y. Nov. 21, 2022), ECF No. 283. All of this shows that AII did not just fail to take *reasonable* steps to avoid imposing undue burden—it refused to take any steps at all. Rule 45(d)(1) therefore mandates that AII bear Peninsula's costs of unnecessarily responding to this wholly improper Subpoena. *See* Mem. 18–21.

### **CONCLUSION**

For the foregoing reasons and those set forth in Peninsula's Brief in Support of Motion to Quash, Peninsula respectfully requests that the Court grant this Motion and require AII to bear Peninsula's fees and costs in responding to it pursuant to Rule 45(d)(1).

<sup>&</sup>lt;sup>19</sup> The sole case AII cites has nothing to do with subpoenas or Rule 45, and thus is inapposite. Opp. 25 n.12 (citing *Am. Sci. & Eng'g, Inc. v. Autoclear, LLC*, 606 F. Supp. 2d 617 (E.D. Va. 2008)).

Dated: December 8, 2022 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 8th day of December, 2022, I electronically filed the foregoing

Reply In Support of Motion to Quash with the Clerk of the court using the CM/ECF system, which

will notify all counsel of record of this filing.

I further hereby certify that I will deliver by electronic mail this document to the following

non-filing users, counsel to the parties in the underlying matter Gref v. American International

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